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(19) (CA) **APPLICATION FOR CANADIAN PATENT** (12)

(54) Automated Sensory Evaluation System

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(73) Same as inventor

(57) 6 Claims

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Notice: The specification contained herein as filed

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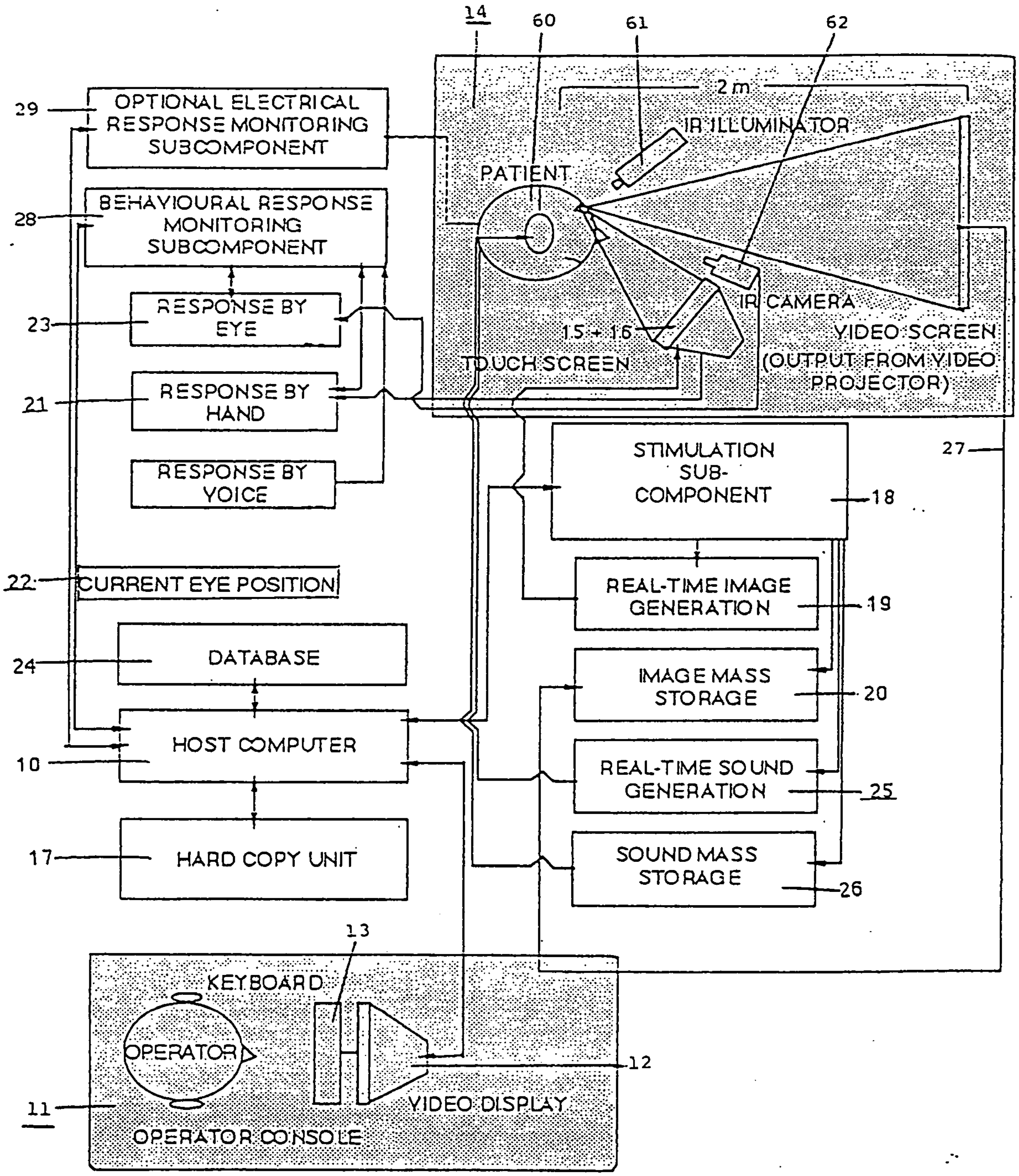
ABSTRACT OF THE DISCLOSURE

An automated multipurpose, real-time apparatus and procedure is provided herein for administration of at least one of visual and auditory stimuli to a patient for the purpose of testing at least one of visual, auditory, attentional and cognitive performance. The apparatus includes at least one of visual and auditory stimulus generation means, response acquisition means, data analysis, archiving and display means and host computer means with memory and mass storage capability. Stimulus generation means, including at least one of auditory and visual stimulus generation means is used to present calibrated, predetermined sequences of test stimuli to the subject under control of the host computer. Both test stimuli and test instructions may be presented using the stimulus generation means. Subject response means are provided for registering behavioral responses from the subject and for relaying these responses to the host computer.



14
60
61
62
2 m
IR ILLUMINATOR
PATIENT
IR CAMERA
1.5 + 1.6
TOUCH SCREEN
VIDEO SCREEN (OUTPUT FROM VIDEO PROJECTOR)
29
OPTIONAL ELECTRICAL RESPONSE MONITORING SUBCOMPONENT
28
BEHAVIOURAL RESPONSE MONITORING SUBCOMPONENT
23
RESPONSE BY EYE
21
RESPONSE BY HAND
RESPONSE BY VOICE
27
STIMULATION SUB-COMPONENT
18
22
CURRENT EYE POSITION
REAL-TIME IMAGE GENERATION
19
24
DATABASE
IMAGE MASS STORAGE
20
10
HOST COMPUTER
REAL-TIME SOUND GENERATION
25
17
HARD COPY UNIT
SOUND MASS STORAGE
26
13
KEYBOARD
OPERATOR
12
11
VIDEO DISPLAY
OPERATOR CONSOLE

THE EMBODIMENTS OF THE INVENTION IN WHICH AN EXCLUSIVE PROPEERTY OR PRIVILEGE IS CLAIMED ARE DEFINED AS FOLLOWS:

1. An interactive diagnostic system of the stimulus-responsive type for evaluating performance levels of a selected at least one of visual, auditory, cognitive, and attentional capacities of a subject, comprising:

(a) a host computer;

(b) generator and displaying means for presenting predetermined sequential stimuli including at least one of visual stimuli and auditory stimuli to said subject in response to selected stimuli modules in said host computer;

(c) subject response means for registering responses of said subject to said sequential stimuli and for relaying said responses to said host computer;

(d) data entry means for instructing said host computer to provide said selected test modules in a predetermined sequences; and

(e) and an analysis, storage and communication means to provide for the analysis of test data, archival storage of recently acquired test data, comparison with previously stored data and the reporting of test results.

2. An automated, multi-purpose, real-time apparatus for administration of stimuli to a patient, for evaluating performance levels of a selected at least one of visual, auditory, cognitive and attentional capacities of a patient, using a host computer including memory and mass storage capabilities for storing data and instructions, said apparatus comprising:

(a) an operator station means having an input display means permitting the system operator to select individual test parameters, individual tests or sequences of tests;

(b) a patient station means having a display means for stimulation of said patient, and a response means for collection of patient responses to said host computer corresponding to stimuli used in a selected test;

(c) stimulus generator module for providing visual auditory stimulation means from both real-time and mass storage;

(d) a response data acquisition peripheral means for capturing patient responses; and

(e) means for recording, archiving, analyzing and reporting patient responses.

3. The apparatus of claim 2, wherein said response data acquisition peripheral means includes an eye position monitor for sensing eye position and movements.

4. An apparatus according to claim 3, wherein said eye position monitor comprises an infra-red light source and an infra-red sensitive closed circuit television camera.

5. An apparatus according to claim 5, wherein the image of said eye generated by said camera yields a position map of said eye.

6. An apparatus according to claim 6, wherein said position map indicates current eye position within a forty-degree frontal field of vision by means of a bit matrix updated by the host computer.

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This invention relates to a system for providing and administering visual and auditory tests to observers to assess at least one of their visual, auditory, cognitive and attentional performance capability, through measurement of behavioural and electrophysiological responses.

People process information about their environment through the senses of vision and hearing. Vision and hearing senses involve the transduction of variations in photic and acoustic energy radiated or reflected from surrounding objects into nervous system signals. As such, these sensory systems also include the neural mechanisms used in the coding and transmission of sensory signals within the nervous system. Because of their importance in every aspect of our life, vision and auditory functions receive much attention in health care services.

The neural substrate that mediates vision and hearing is widely distributed throughout the brain. Consequently, diseases and disorders that effect the brain will often result in visul and auditory abnormalities. Thus, information regarding vision and hearing is of interest and use to the medical diagnostician.

The visual and auditory systems are important channels for providing input for the evaluation of certain aspects of cognition and attentional capabilities in patients. In most neurological and neuropsychological evaluation procedures the patient under examination is given a variety of stimulus-response-type tasks to perform and the nature of the responses obtained in these tasks provides diagnostically useful information.

Rapid and noninvasive evaluation of visual, auditory, cognitive and attentional performance is also desirable in many non-medical applications. For example, there are many applications where it is necessary to evaluate large numbers of individuals in order to detect those among them who may be especially well suited or especially poorly suited for performing

particular tasks requiring a given degree of visual, auditory, cognitive or attentional capacity. Examples of these include screening for air traffic controllers or for operators of transportation equipment.

Automation of such tasks makes possible significant increases in the quantity and the quality of the evaluation data that can be collected in a given period of time; while at the same time increasing test speed, patient comfort and decreasing costs. These are important advantages when considering, for example, the cost of testing of large numbers of individuals or when attempting to monitor individuals at risk in industrial occupations where relatively subtle changes must be detected. As a person's cognitive and attentional capacities are known to vary with changes in the level of fatigue, arousal and the number of other tasks required of the subject at the same time, it is important to be able to evaluate these capabilities under conditions where all of the variables that affect the subjects perormance can be monitored and, where possible, controlled in real time.

Automation also makes possible the use of dynamic logic to branch within a single test and among various tests administered to an individual at speeds not possible using manual test administration and evaluation methods. Further, it makes possible rapid comparison of the subject's response data to those obtained from one or more normative data sets in an on-line database.

There are two main test types bsed upon the kind of responses obtained from the subject. In the first type behavioral responses are obtained from subjects by detecting specific voluntary muscle movements (of the hands, eyes and vocal apparatus) during the execution of certain tasks. In the second type, electrophysiological responses (heart rate, electrically evoked and endogenous responses from the brain, etc.) are

obtained from subjects during the execution of certain tasks as well; however, voluntary muscle movements may or may not accompany these responses. Thus the latter may provide useful information from patients where voluntary muscle movements may be difficult or impossible or where voluntary responses are suspect.

Behavioural tests have the advantages of speed, accuracy, relative technical simplicity and non-invasiveness. Some of the most venerable and diagnostically useful tests of visual and auditory function, for exmple, are behavioural tests. These include the measurement of visual acuity, color vision, visual fields, dark adaptation, pure tone and speech audiometry. Many behavioral tests have been shown to be of use in following the progression and remission of diseases as well as in estimating the amount of residual function after cerebrovascular accidents and trauma. They can also be used to provide objective evaluation of therapeutic interventions (for example, drug treatments) for a variety of disorders that affect vision, hearing, cognition and attention.

Electrophysiological tests offer a somewhat more objective estimate of a limited set of sensory, cognitive and attentional functions. There are three areas of application where visual and auditory evoked electrophysiological responses complement the behavioral tests: (1) as an index of neural mechanisms not amenable to analysis through behavioral means; (2) for more objective confirmation of psychophysical findings in patients who are, for whatever reason, difficult to test; and (3) intraoperative monitoring of sensory status of patients under general anaesthetic.

Although the past decade has shown the emergence of many devices for the analysis of electrical responses from the scalp (and which concentrate mainly, upon the signal processing aspects of the recording technique), few automatic methods have been developed that generate stimuli, control stimulus presentation, collect subject responses and store and manage the data obtained.

U.S. Patent No. 4,474,186 to Ledley et al, issued October 2, 1984, describes a computerized electro-oculographic system with feedback control of stimuli for administration of electro-oculographic tests and visual evoked response tests to a patient, and for automated processing of results derived from such tests. Automated administration of the tests is conducted either under the direct control of the test administrator via an operator control section or under the automated control of a programmed computer with indirect control by the test administrator. It should be noted that such apparatus, although providing automated administration of certain test stimuli to a patient via employment of an operator control console, does not have multi-purpose capability, nor does it provide comparison capability of test results with normative data from a database.

Therefore, it is an object of a principal aspect of the present invention to provide a flexible, automated and multi-purpose, real-time based system for test administration and for recording acquired behavioral and electropsyciological responses in real-time.

Accordingly, by one broad aspect of the present invention, an interactive, automated patient diagnostic system of the stimulus-response type is provided herein for evaluating aspects of at least one of visual, auditory, cognitive, and attentional performance and capacity of a human subject, comprising: (a) a host computer; (b) a stimulus generation and display means for presenting predetermined sequential stimuli including at least one of visual and auditory stimulus to the subject in response to selected stimuli modules in the host computer; (c) subject response means for registering responses of the human subject to the sequential stimuli and for transmitting the responses to the host computer; (d) data entry means for instructing the host computer to provide the selected test modules in a predetermined sequence; and (e) and analysis, storage communication and display

means to provide for the analysis of test data, comparison with previously stored data and the reporting of test results and analysis.

In a specific embodiment of the apparatus of this aspect of the present invention, the apparatus comprises: (a) an operator station means having an input terminal and output display means permitting the system operator to select individual test parameters, individual tests or sequences of tests; (b) a patient station means having a display means for stimulating the patient with visual and auditory stimuli, and a response means for collection of patient responses to a host computer corresponding to the stimuli used in a selected test; (c) a stimulus generator module for providing a stimulation test means through both mass storage and real-time means; (d) a response data acquisition peripheral means for capturing patient responses; (e) means for recording patient responses; (f) a data analysis means for analyzing the data obtained; and (g) database means for comparison of an individual's test results with normative data stored in the database.

The response data acquisition peripheral means includes a hand response monitor, a voice response monitor and an eye movement monitor for sensing and recording eye position and movements. The eye movement monitor preferably comprises an infra-red light source and an infra-red sensitive closed circuit television camera.

The means for administering at least one of visual and auditory stimuli preferably includes both two visual stimulation means, and an auditory stimulation means. Preferably, the visual stimulation means includes a video display screen subtending a visual angle of about 40 degrees at a distance of about 2 metres from the patient and a graphics display terminal, placed within reaching distance of the patient. The auditory stimulation means includes a pair of ear speakers or headphones.

In general terms, the apparatus includes at least one of visual and auditory stimulus generation means, a response acquisition means for hand eye and voice, a data display means and a host computer with memory, mass storage capability and hardcopy capability. The stimulus generator means including at least one of auditory and visual stimulus generation means is used to present calibrated, predetermined sequences of test stimuli to the subject/patient under control of the host computer. Both test stimuli and test instructions may be presented using the stimulus generation means. Subject response means are provided for registering various behavioral responses from the subject and for relaying these responses to the host computer. The apparatus also includes an operator control means by which command and data entry are provided to the host computer. This provides the capability for modification of the specifics of individual test modules and for the assemblage of various selected test modules in a variety of predetermined sequences. The host computer provides data analysis and storage of the results obtained from the administration of tests including comparison means of individual test data to that of group normative data obtained in the same tests.

In the accompanying drawings,

FIGURE 1 is a block diagram of a computerized, real-time visual and auditory stimulator and test system according to one embodiment of the present invention showing its main components; and

FIGURE 2 is a flow-chart explaining the operation of the system of FIGURE 1.

Figure 1 of the drawings shows a block diagram of the computerized test system. It consists of a host computer 10, database 24 and hardcopy unit 17, and an operator console 11 which includes a video display 12 and a keyboard 13. In addition, it consists of a patient station 14 which includes a

visual display 15 within reach of the patient for presenting stimuli and instructions, and a manual response entry terminal 16 (15 and 16 are, preferably, embodied in a single touch screen display). The patient station also has a large format visual display 27 for presenting stimuli and instructions, (subtending a visual angle of about 40 degrees and placed at a distance of 2 metres from the subject's eyes) and a pair of ear speakers or headphones 60 worn by the patient for presenting stimuli and instructions to the patient. Attached to the host computer is a stimulation subcomponent 18, which provides an interface between the visual and auditory stimulii devices of the patient station 14 and the host computer 10. The real-time image generation component 19 provides images for presentation on the visual display 15 while the image mass storage subcomponent 20 provides visual stimuli to the visual display 27. The real-time sound generation subcomponent 25 and the sound mass storage subcomponent 26 provide auditory stimuli to the patient's headphones 60. The behavioral response monitoring subcomponent 28 provides an interface for the acquisition of eye 23, hand 21 and voice 22 responses by the host computer 10.

Should it be also desirable to include, in the system, electrophysiology response monitoring, for example as taught by Ledley et al in United States Patent 4,474,186, electrical response monitoring means 29 would be necessary.

With reference to Figure 2 of the drawings, the flow-chart explaining the overall system operation will now be described. After log-on 30 the operator may choose one of three modes via mode select 31. The three modes of operation are system development 32, operator training 33, and patient testing 34. The first two modes are self-explanatory. For example, the system development mode 32 is used to enter commands and data for new tests, and to establish new test batteries, and the like. It is also used to create specific databases to which incoming test

data will be compared. The operational mode proper is called the patient testing mode 34, which, when selected, displays a master menu 35, with at least three choices: either a menu 36 of single tests, a menu 37 of test batteries, or establishment of a new patient file 38. The latter, when selected, permits the operator to enter new patient data which may result in the updating of one or more of the files in the patient data base 39. Once the test batteries menu 37 has been displayed and a particular test battery "J" has been selected, the system retrieves the test files 40 of that battery and begins with the test at the top of the battery "J" file at next test 41 by executing that test's generation file 42, which commences a sequence of timed commands and signal timing triggers 43 to activate stimulus generation peripherals 44 (corresponding to 18 in Figure 1), and response data acquisition peripherals 45 (corresponding to 29 in Figure 1). The collected data are analyzed at 46 in light of the stimulus generated, the patient data, and the test database(s) (that could include normative data), and a decision rule is used to determine the validity of the test and data at decision block 47. For example, if a large number of stimulus trials are not responded to within preestablished critical limits controlled by timing triggers 43, the test data are not considered as a valid measure of the function of under test and the test is then repeated 48. If the data and test administration are found to be valid, then the system invokes the next test generation file, and so on until the final test has been completed. The system may also invoke an update of the test data base 49. The results are then archived, analyzed and displayed. After the last test is completed the results may be printed 51. The single test menu 36, had it been selected, would simply enable the operator to retrieve a single test 50 and administer it in the same manner via the same routines. However, no linkage would be made to any other test upon completion.

The determination of the validity of individual responses in may behavioral tests requires the evaluation of eye position and/or eye movement monitoring. In Figure 1, a preferred sub-system for the acquisition of eye position is shown. The host computer 10, upon executing a given test generation file, controls the generation of visual images to be presented to either to the touch screen display 15 or to the large format visual display 27. The host computer 10 then retrieves information about the position of the subject's eye from the eye position subcomponent 23. An infra-red sensitive camera with a telephoto lens 62 is focussed upon the pupil of the subject's right eye while the eye is illuminated with low-level infra-red radiation through the use of an infra-red illuminator 61. The output of the camera is the spatial characteristics of the infra-red image of the pupil and this information 64 is passed to the host computer 10. The current eye position 64 is resolved to within about 0.25 degrees about the 40 degree field of view, which is sufficient, for the purposes of this system, to monitor direction of gaze during testing. It is possible, using this system, to edit out of the test data trials in real-time those where the eyes were not directed in the appropriate position.

An example showing interaction with the system for a single psychophysical test will now be described to illustrate the procedures generally common to many such tests, which differ mainly in the details of the stimuli presented and in the nature of the operator's and patient's instructions.

[OPERATOR SCREEN]

---

[Hospital Laboratory Name]        Operator ID:  [Name]

Name of Patient Currently on System:  [Name]
Patient File ID .....................[xxxx]

Time: xx xx xx                          Date:  xx xx xx

SINGLE TEST MENU

Psychophysical Tests:

1.........Variable-contrast snellen acuity tests

2.........Spatiotemporal contrast sensitivity tests

3.........Eye movement control system analysis tests

4.........Pure tone audiometry tests

5.........Dichotic listening tests

6.........Static and dynamic perimetry tests

7.........Complex visual pattern recognition tests

8.........Driver vision test

(Optional) Evoked Potential Tests

9.........Stimulus-Evoked Cortical Potential tests

10........Stimulus-Evoked Electroretinogram tests (ERG)

PLEASE ENTER CHOICE ---- > 2    < RET >    TO MASTER MENU

---

For this example, the operator has decided to administer one of the spatiotemporal contrast sensitivity tests (#2). Another menu comes onto the operator's screen offering the various versions of this test. From this menu onward throughout the testing session two additional control options become available to the operator. (1) < RETURN > to invoke default choices to individual questions and (2) < ESC > to invoke default options for entire sections of questions during the set up procedure.

The setup file contains information regarding the names of the stimulus graphics files used in the particular test under consideration, control parameters used for modifying stimulus

characteristics depending upon the patient's responses. In addition, parameters for patient performance optimization can be provided in this file--including the use of eye position monitoring, feedback to the patient regarding test performance, and arousal and attention regulation through the use of visual or auditory signals. It also contains the file names of two additional files--one for text for patient instructions and prompts and one for operator prompts.

[OPERATOR SCREEN]

---

Test #2

Spatiotemporal Contrast Sensitivity Test

Enter Test Initialization filename: ________ RETURN
(Default)

Enter Patient Instruction Set filename: ______ RETURN
(Default)

Enter Operator Instruction Set filename: ______ RETURN
(Default)

Initial Operator Instructions:

1. Position Patient in testing booth. Ensure that patient's glasses do not interfere with eye-movement monitor and are comfortable. Adjust seat so patient can reach the touch screen.

---

10 MINUTES OF DARK ADAPTATION IS REQUIRED PRIOR TO THIS TEST

---

2. Press RETURN when ready to deliver patient instruction set:

< RETURN >

Subject Instructions Page 1 now presented on patient monitor.

Press RETURN when ready to begin adaptation.

< RETURN >

Pre-Adaptation in progress (X minutes remaining)

Note that the operator chose to use the default filenames but could have entered others, invoking "customized" files. The instruction file is written in "pages" and contains special characters (transparent to the instruction reader) that delimit the amount of information presented on a single "page" and link these instructions to graphics examples.

The patient display monitor always has some type of pattern present--except when darkness is required for a test. This is true even when a test is not being administered. Audio information is presented during waiting periods to help maintain patient arousal levels.

The subject's instructions appear on the patient display monitor and on the operator's monitor. At this point feedback from the patient is useful regarding comprehension of the instructions. The patient instruction set is always linked to a short "dry run" of the experiment. An example dry run (with patient responses in brackets) follows:

[PATIENT SCREEN]

---

Welcome to the
[(Hospital Laboratory Name)]

In this test there are two windows on the screen that you are to watch. One window has a pattern in it while the other is blank. Please press the left button on the touch screen if you see the pattern on the left side and the right button if you see the pattern on the right. If you don't see the pattern on either side, try to guess.

Here is an example:

[the test pattern appears in left window]

"In this case, the pattern is seen in the left window so you press the left button. PRESS THE LEFT BUTTON NOW.

(button is pressed by patient)

"Correct. Get ready for the next one."
(after a few seconds)
"This ends the practice runs."

If there is dark adaptation before the test, something like the following will be presented:

"Please wait for a few minutes to adapt your eyes"
At this point an operator prompt will start the adaptation session and a timed signal will alert the patient near the end of the adaptation session.

After the adaptation period is completed, the following prompt will be presented through the headphones and on the video screen:

"Test begins in 10 seconds. Watch the screen and respond when requested to do so in the same way as in the example you just carried out."

At this point the test begins.

The actual testing task in this case, consists of a large number of trials of monocular viewing (i.e., each eye tested separately) of a sinusoidal contrast grating of fixed spatial frequency and orientation presented in only one of two "window areas" on the video graphics display. On each trial the patient must decide in which of the window areas (say, in this example, the left or the right) a pattern is present. The orientation, rate of temporal modulation, spatial frequency and luminance contrast of the pattern is varied randomly as is the location of presentation of the pattern on each trial.

After every stimulus trial is presented, the patient is provided with feedback (typically, auditory feedback for visual tests and vice versa) on whether or not his response was correct. This aids in maintaining arousal level and interest by providing a running estimate to the patient of his performance somewhat in the manner of an arcade game.

Threshold for detection of the "pattern" is estimated for each of the parameter ranges that are randomly sampled in the test: spatial frequency, orientation, temporal frequency; with spatial modulation (i.e., contrast) of the pattern being the dependent variable.

During the test a number of measures are taken that are relevant to the determination of the patient's visual sensitivity and the evaluation of the quality of data obtained from the

patient. By monitoring eye position during stimulus presentation it is possible to know if the patient is looking at the pattern or not, and by monitoring patient response time within and between test trials and comparing these data to previously obtained response times from the patient, an estimate of the level of fatigue at that point in the test can be obtained.

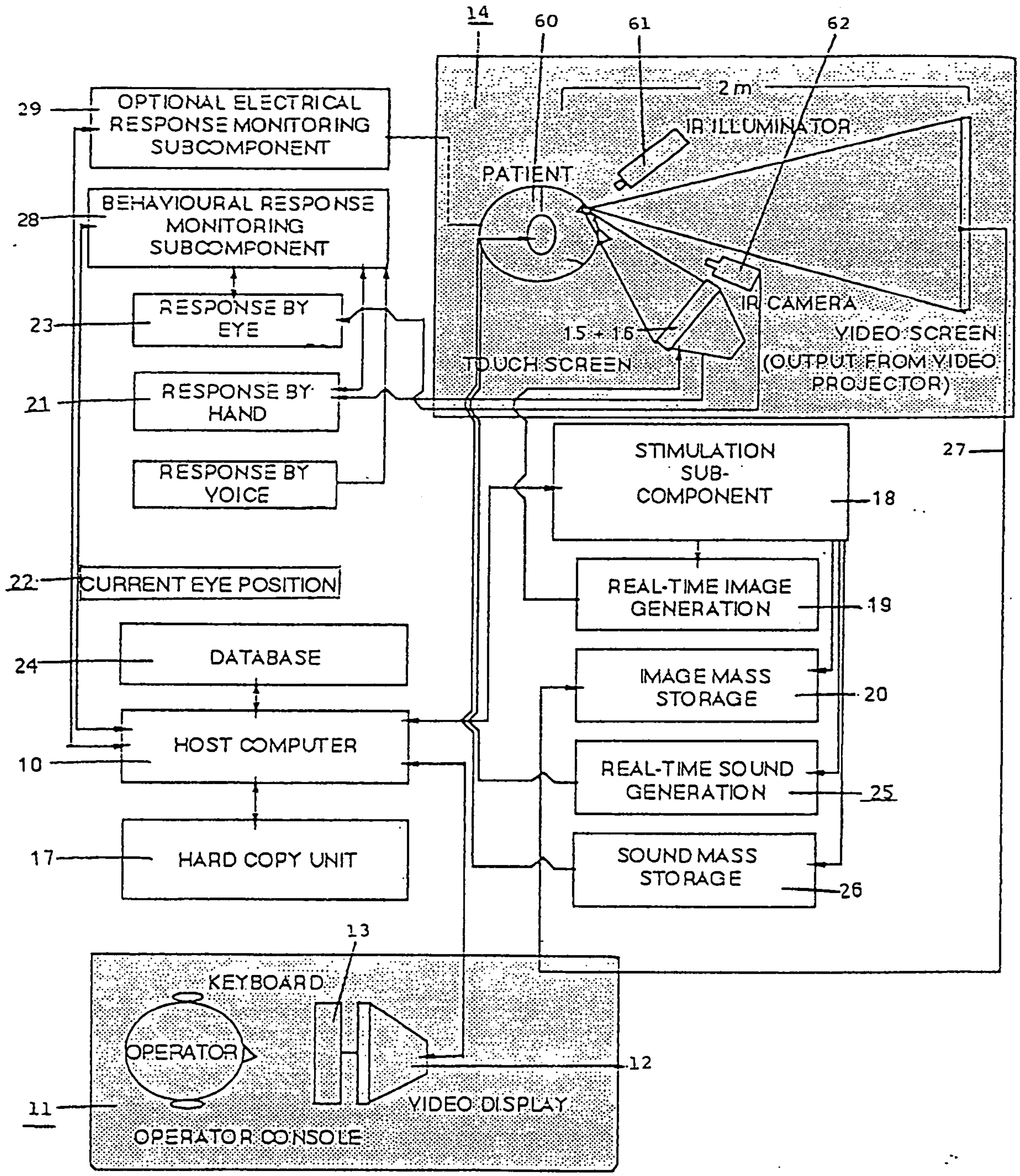


FIGURE 1

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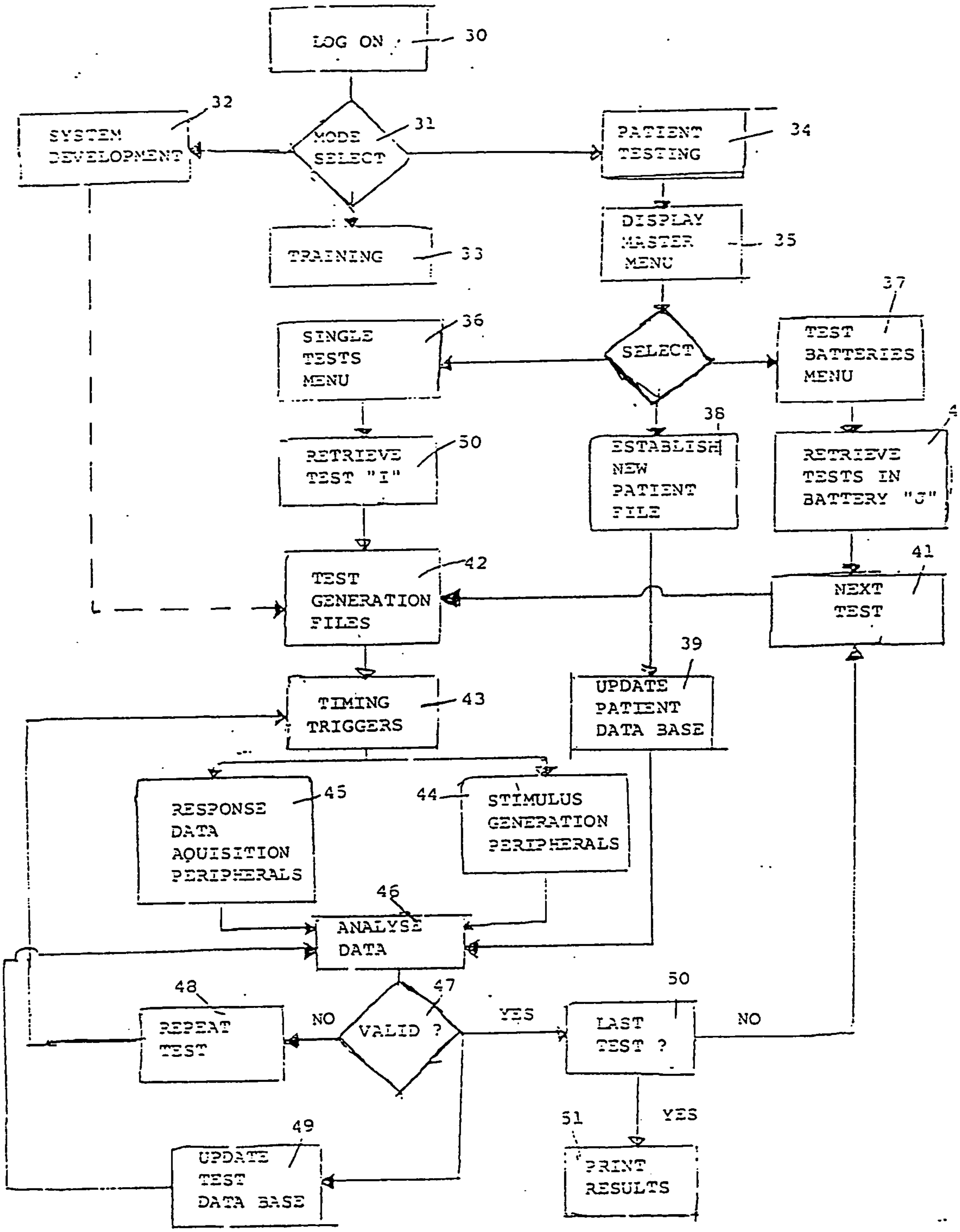


FIGURE 2

McFadden, Fincham, Marcus & Allen